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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,095	09/18/2003	Robert P. Hammer	Hammer 0212.1	6953

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PATENT DEPARTMENT
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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
08/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,095	HAMMER ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-18,20,21 and 51-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-18,20,21,51-53,55 and 56* is/are rejected.

7)☒ Claim(s) *54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 7, 2007 has been entered.

2. In view of the papers filed August 7, 2007, the inventorship in this nonprovisional application has been changed by the deletion of Jed P. Aucoin and Robin L. McCarley as inventors.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

3. Applicant is advised that should claim 1 be found allowable, claim 56 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 56 is identical in scope with independent claim 1, upon which it depends. Applicants indicated in their remarks that they intended to return claim 1 to the scope it had upon filing the application (with the exception of newly added part (f)); however, claim 1 was amended on December 23, 2005 to include the limitation of originally-filed claim 19, which is the limitation present in new claim 56.

4. Claims 1, 4, 7-18, 20, 21, 51, 52, 55, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The interpretation of the new limitation in claim 1, part (f) is unclear. Firstly, the aggregation-inducing sequence referred to in part (f) is recited in the preamble to claim 1 as part of an intended use limitation. Applicants appear to be limiting the scope of the claimed compounds depending upon an intended use limitation. However, it is well-settled case law that intended use limitations do not distinguish over prior art which otherwise anticipates a claimed product. Further, it does not appear that Applicants intend to exclude all compounds in which X_{aa1}, X_{aa2}, and X_{aa3} are Lys, Val, and Phe, respectively, or are Leu, Phe, Ala, respectively. Note that Applicants' claims 4 recites a compound in which X_{aa1}, X_{aa2}, and X_{aa3} are Lys, Val, and Phe, respectively. Further, Applicants' claims appear to embrace compounds in which X_{aa1}, X_{aa2}, and X_{aa3} are Lys, Val, and Phe, respectively, and which Applicants intend to use inhibit the toxicity of amyloid proteins or amyloid peptides which comprise, as alternating amino acids, the sequences Lys-Val-Phe and Leu-Phe-Ala. See, e.g., paragraph [0036]. Apparently, a compound may or may not be encompassed within the scope of the claim depending upon whether someone's intended use coincides with that recited in part (f). It is not clear whose intended use triggers the limitation of Applicants' claim 1, part (f). A claim whose scope is dependent upon an unspecified person's intent is indefinite. Secondly, the limitation recites "then X_{aa1}, X_{aa2}, and X_{aa3} are identical neither to the sequence Lys-Val-Phe nor to the sequence Leu-Phe-Ala". However, X_{aa1}, X_{aa2}, and X_{aa3} are defined in the claim as being individual amino acids, and thus can never be identical to the sequences Lys-Val-Phe or Leu-Phe-Ala. For that matter, according to the peptidyl sequence formulae recited in claim 1, X_{aa1},

X_{aa2}, and X_{aa3} are not even contiguous amino acids which form a sequence. The wording of the "then..." clause is at best awkward.

5. Claims 53 and 54 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/412,081 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

Instant claims 1, 4, 7-18, 20, 21, 51, 52, 55, and 56 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/412,081 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose all of the generic formulas recited in instant claims 1 and 51; does not disclose the additional functionalities of instant claim 1, part (d); does not disclose the size limitations of instant claim 1, part (e); does not disclose compounds corresponding to SEQ ID NOS:5, 6, and 7; does not disclose aggregation-inducing sequences corresponding to SEQ ID NOS:9-16 or Q_m where m is an integer from 25 to 45; and does not disclose combining the compounds with a pharmaceutically acceptable carrier in general. Note that unless a claim is limited exclusively to subject matter disclosed in a priority application, the claim is not entitled to the benefit of the filing date of the priority application. See MPEP 201.11(I) and (VI).

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 7, 8, 20, 51, 52, 55, and 56 are rejected under 35 U.S.C. 102(b) and claim 53 is rejected under 35 U.S.C. 102(a) as being anticipated by the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001). The Fu et al article teaches Applicants' elected peptide, Lys-Digb-Val-Dbzg-Phe-Dpg-$(Lys)_6$-NH_2. See page 239, column 1.

This peptide corresponds to, e.g., the seventh peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6. This peptide corresponds to, e.g., the eleventh peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, X_{aa3} is Lys, and $(S)_n$ is Lys_5-NH_2 where n=5. This peptide also corresponds to, e.g., the first peptidyl sequence of claim 53 wherein X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, and $(S)_n$ is Dpg-Lys_6-NH_2 where n=7. Note that Applicants' definition of $(S)_n$ states that the hydrophilic region comprises hydrophilic amino acids or other hydrophilic groups, i.e. can comprise non-hydrophilic amino acids and groups as long as the region as a whole is hydrophilic. This peptide also corresponds to, e.g., the second peptidyl sequence of claim 53 wherein X_{aa1} is Lys, Y_{AA1} is Digb, X_{aa2} is Val, Y_{AA2} is Dbzg, X_{aa3} is Phe, n=0, and the C-terminal end comprises an additional functionality (i.e. Dpg-Lys_6-NH_2) that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality.

Applicants' claims do not recite an absolute prohibition that X_{aa1}, X_{aa2}, and X_{aa3} can not be Lys, Val, and Phe, respectively, or Leu, Phe, and Ala, respectively. Rather, Applicants have modified the intended use limitation of claim 1 in an effort to distinguish over the peptide of the

Fu et al article. However, the peptide of the Fu et al article otherwise meets the structural limitations set forth in the rejected claims, and an intended use limitation does not distinguish over a prior art product which otherwise anticipates a claimed product. As an alternative, in the peptide of the Fu et al article, X_{aa1}, X_{aa2}, and X_{aa3} are not identical to a sequence Lys-Val-Phe or Leu-Phe-Ala, and accordingly the limitation set forth in Applicants' claim 1, part (f), does not distinguish over the peptide of the Fu et al article. See also the above rejection under 35 U.S.C. 112, second paragraph, raising issues as to how the limitation set forth in part (f) is to be interpreted.

8. Claims 1, 7, 8, 20, 21, 51, 52, 55, and 56 are rejected under 35 U.S.C. 102(a) as being anticipated by the Fu dissertation (Louisiana State University, December 2002). The Fu dissertation teaches the peptide AMY-3 at page 126 which comprises the same peptidyl sequences recited in instant claim 1. For example, AMY-3 of the Fu dissertation corresponds to the seventh peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, and (S) is Lys and n=7. Alternatively, AMY-3 corresponds to the eleventh peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, X_{aa3} is Lys, (S) is Lys, and n=6. In view of the similarity in structure between the peptide of the Fu dissertation and Applicants' claimed peptidyl sequences, the peptide of the dissertation inherently will be capable of inhibiting the toxicity of an amyloid protein or amyloid peptide to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present the peptide of the Fu dissertation and Applicants' claimed compounds to shift the burden to Applicants to provide evidence that the claimed compounds are unobviously different than the peptides of the Fu dissertation. Note that patentability is not imparted to product claims merely

upon the employment of descriptive language not chosen by the prior art. In re Skoner, 186 USPQ 80, 82 (CCPA 1975). The discovery of a new property or use for a previously known compound can not impart patentability to claims drawn to the compound. In re Schoenwald, 22 USPQ2d 1671 (CAFC 1992). The Fu dissertation also teaches the peptide AMY-1, which corresponds to Applicants' elected SEQ ID NO:4 and which is combined with a phosphate-buffered aqueous solution. See pages 103 and 108. The AMY-1 peptide corresponds to corresponds to, e.g., the seventh peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6. This peptide corresponds to, e.g., the eleventh peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, X_{aa3} is Lys, and $(S)_n$ is Lys_5-NH_2 where n=5.

9. Claims 1, 7, 8, 20, 21, 51, 52, 55, and 56 are rejected under 35 U.S.C. 102(a) as being anticipated by the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003. The Aucoin oral presentation, as evidenced by the presentation notes supplied in the Information Disclosure Statement filed September 18, 2003, disclosed peptides AMY-1 and AMY-3 which correspond to Applicants' claimed compounds of SEQ ID NOS:4 and 6, respectively. The

peptides are combined with a phosphate-buffered aqueous solution, which corresponds to Applicants' pharmaceutically acceptable carrier.

AMY-3 corresponds to the seventh peptidyl sequence of amended claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, and (S) is Lys and n=7. Alternatively, AMY-3 corresponds to the eleventh peptidyl sequence of claim 1 wherein Y_{AA1} is Dpg, X_{aa1} is Phe, Y_{AA2} is Dbzg, X_{aa2} is Val, Y_{AA3} is Dibg, X_{aa3} is Lys, (S) is Lys, and n=6. AMY-1 corresponds to corresponds to, e.g., the seventh peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, and $(S)_n$ is Lys_6-NH_2 where n=6. This peptide corresponds to, e.g., the eleventh peptidyl sequence of amended claim 1 wherein the N-terminal end comprises Lys that does not adversely affect the compound's ability to inhibit the toxicity of an amyloid protein or amyloid peptide as compared to an otherwise identical compound lacking such additional functionality, Y_{AA1} is Digb, X_{aa1} is Val, Y_{AA2} is Dbzg, X_{aa2} is Phe, Y_{AA3} is Dpg, X_{aa3} is Lys, and $(S)_n$ is Lys_5-NH_2 where n=5.

The Aucoin oral presentation satisfies the requirement of 35 U.S.C. 102(a) that an invention be "known... by others in this country" because the identity of the presenter is different than the inventorship of the instant application, and any difference in authorship/inventorship satisfies the statutory requirement of "by another". See MPEP 2132(III). See also Ecolochem Inc. v. Southern California Edison, 56 USPQ2d 1065, 1071 (CAFC 2002), where the court acknowledges that oral presentations can satisfy the requirements of 35 U.S.C.

102(a). This rejection could be overcome, e.g., by the submission of a declaration under 37 CFR 1.132 showing that the subject matter of the presentation was derived from the instant inventors and was therefore not "by another". See MPEP 715.01(c), 716.10, and 2136.05.

Note that the Aucoin oral presentation is not considered to be a printed publication because insufficient evidence is of record as to whether printed copies, slides, etc. of oral presentation were made available and/or whether members of the public had time to make copies of the disclosed subject matter. Compare In re Klopfenstein, 72 USPQ2d 1117 (CAFC 2004).

10. Applicant's arguments filed August 7, 2007 have been fully considered but they are not persuasive.

At page 2, second-to-last paragraph, of the Remarks, Applicants state that claim 1 now reads the same as it did when originally filed, except for the addition of new part (f). As noted in section 3 above, the examiner does not agree. Claim 1 was amended on December 23, 2005 to include the limitation of originally-filed claim 19. Further, claim 1 was amended on June 27, 2006 to recite that n is from 4 to 10, in order to overcome, e.g., a rejection based upon the Fu et al article (J. Org. Chem., Vol. 66, pages 7118-7124). Both of these amendments remain as limitations in claim 1.

The rejection of claim 1 and certain of its dependent claims over the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001) is maintained in view of the uncertainty of the interpretation of part (f), newly added to claim 1. See also the above rejection under 35 U.S.C. 112, second paragraph.

Claim 53 remains rejected under 35 U.S.C. 102(a) as being anticipated by the Fu et al article (Organic Letters, Volume 4, pages 237-240, published on Web 12/22/2001). The

declaration by Hammer filed August 7, 2007 is insufficient to show that the Fu et al article is not "by others". In particular, the Hammer declaration at section 5 states that McLaughlin and Hammer are the inventors of rejected claim 53. The Hammer declaration at paragraphs 7(b) and 7(c) states that McLaughlin, Fu, Miller, and Hammer are the inventors of the peptide AMY-1, i.e. the subject matter disclosed in the Fu et al article and relied upon by the examiner in the rejection. Accordingly, the subject matter disclosed in the Fu et al article and relied upon by the examiner in the rejection, i.e. the AMY-1 peptide, is "by others" because four inventors are different than two inventors (see MPEP 2132(III)). The subject matter is therefore available as prior art against instant claim 53 under 35 U.S.C. 102(a). Further, the Hammer declaration's assertions in paragraphs 7(b) and 7(c) are contradicted by the implications/assertions in paragraphs 8(d) and 9(b) that McLaughlin and Hammer are the inventors of the AMY-1 peptide. In the absence of a consistent set of statements as to who invented the subject matter disclosed in the applied references, the examiner can not make a determination that the disclosed subject matter was not "by others" and is therefore not available as prior art under 35 U.S.C. 102(a).

The anticipation rejection over the Fu dissertation (Louisiana State University, December 2002) is maintained. The Fu dissertation is applied against Applicants' claims because of the dissertation's disclosure of the peptides AMY-3 and AMY-1. Section 8 of the Hammer declaration does not explicitly state who are the inventors of these two peptides. Paragraph 8(d) states that any disclosure by the Fu Dissertation of subject matter encompassed by the rejected claims, other than disclosure of peptide synthesis, was derived from McLaughlin and Hammer. This paragraph therefore implies that peptides AMY-3 and AMY-1 were invented by McLaughlin and Hammer. However, at least for peptide AMY-1, this implication is contradicted

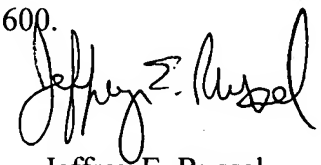
by the statement in paragraphs 7(b) and 7(c) that McLaughlin, Fu, Miller, and Hammer are the inventors of the peptide AMY-1. The Hammer declaration does not sufficiently establish the inventorship of the subject matter disclosed in the Fu dissertation and relied upon by the examiner in the prior art rejection.

The anticipation over the Aucoin oral presentation, "Dissection of an Amyloid Aggregation Inhibitor", 225th American Chemical Society conference, New Orleans, LA, March 23-27, 2003, is maintained. As a factual matter, with respect to paragraph 9(b), it should be noted that the Aucoin oral presentation is not cited due to its disclosure of the peptide AMY-2. The peptide AMY-2 is not embraced by the instant claims, which require the presence of an $(S)_n$ group where n=4-10. Paragraph 9(b) states that McLaughlin and Hammer are the inventors of peptides AMY-1 and AMY-3. However, at least for peptide AMY-1, this statement contradicts the statement in paragraphs 7(b) and (c) that McLaughlin, Fu, Miller, and Hammer are the inventors of the peptide AMY-1. In the absence of consistent statements with respect to the inventorship of the disclosed subject matter relied upon in the rejection, the Hammer declaration can not be relied upon to show that the disclosed subject matter is not "by others".

11. Claim 54 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

August 16, 2007